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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,812	12/08/2005	Kazuyuki Oku	OKU11	7345
1444	7590	03/17/2008		
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER	
			BLAND, LAYLA D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/559,812	<b>Applicant(s)</b> OKU ET AL.
	<b>Examiner</b> LAYLA BLAND	<b>Art Unit</b> 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 January 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 9 and 11-13 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 9, 11-13 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1668)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

#### **DETAILED ACTION**

This office action is a response to Applicant's amendment submitted January 16, 2008, wherein claims 1-8, 10, and 14-26 are cancelled and claims 9 and 11-13 are amended. Claims 9 and 11-13 are currently pending and are examined on the merits herein.

In view of the cancellation of claims 1-8, 10, and 14-26, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's arguments submitted January 16, 2008, the rejection of claims 9 and 11-13 under 35 USC 112, second paragraph, as being indefinite with respect to "associated complex," is withdrawn.

The following rejections of record are maintained:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US 6,159,529, December 12, 2000, of record) and Maruta et al. (US 6,017,899, January 25, 2000, of record) in view of Cook et al. (Carbohydrate Research, 31 (1973) 265-275, of record).

Uchida et al. teach that trehalose-containing agents enhance the level of salty or delicious taste and can be substituted for conventional seasonings such as table salt [column 5, lines 38-41]. Usually the food products contain trehalose in amount of at least 1.5 w/w% and sodium chloride should be present in an amount of at least 1.5% [column 3, lines 16-33]. Trehalose can be used with mineral-enriching agents such as calcium chloride [column 5, lines 50-57]. A solution of sodium chloride and trehalose was prepared in water and it was found that trehalose enhanced the salty taste of the solution [column 6, lines 15-67]. A table salt like agent was prepared from 80 parts by weight of trehalose, 10 parts by weight of potassium chloride, 7 parts by weight of calcium chloride, and 3 parts by weight magnesium sulfate [column 14, lines 14-33]. This composition has a salty taste and supplies calcium and magnesium, which would be beneficial to patients with circulatory disease [column 14, lines 14-33].

Maruta et al. teach non-reducing saccharides ( $\alpha$ -glucosyl trehalose,  $\alpha$ -maltosyl trehalose,  $\alpha$ -maltotriosyl trehalose,  $\alpha$  maltotetraosyl trehalose and  $\alpha$ -maltopentaosyl trehalose [column 19, lines 42-53]) which can be used as taste-improving agents, quality-improving agents, stabilizers, excipients and dessicants in food products and other products [column 12, lines 32-38]. They have a sweetness which harmonizes well with materials having salty tastes and are highly acid- and heat-resistant [column 12, lines 59-67].

Neither Uchida et al. nor Maruta et al. teach a crystalline complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and a metal ion compound.

Cook et al. teach crystalline  $\alpha,\alpha$ -trehalose-calcium bromide [see abstract]. The crystals were obtained by evaporating an aqueous solution that contained an approximately equimolar mixture of  $\alpha,\alpha$ -trehalose and calcium bromide [page 266, Experimental]. In the crystal structure of the complex, the calcium ion is surrounded by a coordination polyhedron composed of seven oxygen atoms [page 269, last sentence].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and a metal ion compound. Both metal-trehalose complexes and  $\alpha$ -glycosyl trehalose compounds are known in the art as taste-improving agents which harmonize well with salty tastes, as taught by Uchida et al. and Maruta et al. Furthermore, Maruta et al. teach that  $\alpha$ -glycosyl trehalose compounds and trehalose can be arbitrarily used in compositions such as food products and taste-improving agents [column 34, lines 53-59].

The skilled artisan would be motivated to crystallize the resulting metal-  $\alpha$ -glycosyl trehalose complex in order to obtain a product of superior purity. The skilled artisan would have an expectation of success because a complex of  $\alpha,\alpha$ -trehalose with calcium bromide has been crystallized before, as taught by Cook et al. The skilled artisan would understand that a calcium chloride complex could be prepared using the guidance provided by Cook et al. for the preparation of a calcium bromide complex.

***Response to Arguments***

Applicant's arguments filed January 16, 2008 have been fully considered but they are not persuasive.

Applicant argues that  $\alpha$ -glycosyl- $\alpha,\alpha$ -trehalose is a derivative of  $\alpha,\alpha$ -trehalose and thus should be distinguished, and that the prior art does not teach or suggest that  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose may form an associated complex with calcium chloride.

The prior art teaches that trehalose forms a complex with calcium bromide. The  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose compounds taught by Maruta et al. retain the trehalose moiety that is known to form a complex, so the skilled artisan would expect the  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose to also form a complex.

Applicant argues that Cook teaches calcium bromide rather than calcium chloride.

The skilled artisan would understand that calcium bromide and calcium chloride are both halogen salts of calcium and thus complex formation with calcium chloride would be reasonably likely to occur in a substantially same or similar function and fashion as with calcium bromide.

Claims 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oku et al. (WO 03/016325 A1, February 27, 2003, using the English language equivalent US 2004/0209841, October 21, 2004, of record) in view of Maruta et al. (US 6,017,899, January 25, 2000, of record).

Oku et al. teach associates of trehalose and metal compounds which have improved deliquescence, reducing power, oxidizing power, and solubility [see abstract]. The associates are formed by mixing trehalose with metal ion compounds in a solvent such as water or in solid forms [0027]. A crystalline associate was formed from one

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mole of calcium chloride dehydrate and one mole of trehalose in aqueous solution [0067 and 0068]. The resulting compounds have improved deliquescence, which gives them good handleability on preserving or admixing with various compositions [0163].

Magnesium and calcium are required for enzymatic reactions in human bodies but metal ion compounds taste unpleasant [0003 and 0004].

Oku et al. do not teach a composition comprising a complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$  trehalose and a metal ion compound.

Maruta et al. teach non-reducing saccharides ( $\alpha$ -glucosyl trehalose,  $\alpha$ -maltosyl trehalose,  $\alpha$ -maltotriosyl trehalose,  $\alpha$  maltotetraosyl trehalose and  $\alpha$ -maltpentaosyl trehalose [column 19, lines 42-53]) which can be used as taste-improving agents, quality-improving agents, stabilizers, excipients and dessicants in food products and other products [column 12, lines 32-38]. They have a sweetness which harmonizes well with materials having salty tastes and are highly acid- and heat-resistant [column 12, lines 59-67].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a crystalline complex of an  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and a metal ion compound. Metal-trehalose complexes are known to be useful in food compositions which contain calcium and  $\alpha$ -glycosyl  $\alpha,\alpha$  trehalose compounds are known to be taste-improving agents. The skilled artisan could combine these two teachings to arrive at a food additive that could easily be predicted to be a taste-improving agent.

***Response to Arguments***

Applicant's arguments filed January 16, 2008 have been fully considered but they are not persuasive.

Applicant argues that  $\alpha$ -glycosyl- $\alpha,\alpha$ -trehalose is not the same as  $\alpha,\alpha$ -trehalose and that that one of ordinary skill in the art would not expect success in forming the claimed complex.

This argument has been addressed above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9 and 11-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 14 of U.S. Patent No. 6,017,899 in view of Uchida et al. (US 6,159,529, December 12, 2000, of record). The

difference between the instant claims and those of U.S. Patent No. 6,017,899 is that the instant claims are drawn to crystalline complexes of  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose with a metal ion compound and the claims of U.S. Patent No. 6,017,899 are drawn to  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose compounds. However, Uchida et al. teach metal ion complexes of  $\alpha,\alpha$ -trehalose which have advantages as food additives, as do the currently claimed compositions, as discussed above. Thus, the instant claims are considered obvious over the claims of U.S. Patent No. 6,017,899.

***Response to Arguments***

Applicant's arguments filed January 17, 2008 have been fully considered but they are not persuasive.

Applicant argues that the instant claims are not drawn to trehalose.

This is substantially the same argument made above in reference to the rejection over Uchida et al. and Maruta et al. in view of Cook et al. The argument has been addressed following that rejection, above.

Claims 9 and 11-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 and 38 of copending Application No. 10/486,328 in view of Maruta et al. (US 6,017,899, January 25, 2000, of record) and Cook et al. (Carbohydrate Research, 31 (1973) 265-275, of record).

The difference between the instant claims and those of copending Application No. 10/486,328 is that the instant claims are drawn to metal complexes of  $\alpha$ -glycosyl

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$\alpha,\alpha$ -trehalose with a metal ion compound and the claims of copending Application No. 10/486,328 are drawn to metal complexes of  $\alpha,\alpha$ -trehalose. However, Maruta et al. teach that  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose compounds have desirable properties as food additives, as do the currently claimed compositions, as discussed above, and Cook et al. teach crystallization of a  $\alpha,\alpha$ -trehalose -calcium ion complex. Thus, the instant claims are considered obvious over the claims of copending Application No. 10/486,328.

This is a provisional obviousness-type double patenting rejection.

***Response to Arguments***

Applicant's arguments filed January 17, 2008 have been fully considered but they are not persuasive.

Applicant argues that  $\alpha$ -glycosyl- $\alpha,\alpha$ -trehalose is not the same as  $\alpha,\alpha$ -trehalose and that one of ordinary skill in the art would not expect success in forming the claimed complex.

This is substantially the same argument made above in reference to the rejection over Uchida et al. and Maruta et al. in view of Cook et al. The argument has been addressed following that rejection, above.

Applicant argues that the claimed complexes provided superior properties compared to similar complexes with maltitol and trehalose, noted on page 3, lines 14-18 of the instant specification.

Page 3, lines 14-18 of the specification, says that associated complexes showed different properties from the intact metal compounds. This does not appear to support Applicant's argument.

Applicant argues that deliquescent properties of calcium chloride are reduced by forming associated complexes of  $\alpha$ -glycosyl  $\alpha,\alpha$ -trehalose and calcium chloride.

This is not unexpected. Oku et al. teach that associates of trehalose and metal compounds have improved deliquescence. Furthermore, Schenz et al. (4,541,872, September 17, 1985) teach that sugar-calcium chloride complexes are non-hygroscopic [column 1, line 65 – column 2, line 16].

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/  
Examiner, Art Unit 1623

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner, Art Unit 1623